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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,955	09/05/2003	Armand Malnoe	88265-6980	8820

28765 7590 06/15/2004

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EXAMINER	
KHARE, DEVESH	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,955	MALNOE ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *14-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. PCT/EP02/02862.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/22/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *5/26/04* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a food composition comprising a molecule that stimulates energy metabolism of the cell and an antioxidant and/or the further antioxidant, classified in classes 514, 536 and 424, subclass various.

II. Claims 14-25, drawn to a method for preventing or delaying mitochondria dysfunction occurring in a mammal during aging with the compositions of Group I, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons: Groups **I to II** are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with another materially different product i.e. a method for preventing or delaying mitochondria dysfunction occurring in a mammal during aging can be practiced with another materially different product such as carnitine and an oxidant, see U.S. patent 6,335,361.

Although the inventions are classified in the same class and sub-class, searching the two groups of inventions constitutes a burdensome search, as a thorough search comprises a search or foreign patents and non-patent literature as well as the appropriate U.S. patent classifications. Because these inventions are distinct for the

reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper. It is noted that examination of the two independent and distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims, which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP § 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During telephone conversation with applicant's attorney Allan Fanucci on 05/26/04, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-13 are before the examiner and an action on the merits of said claims is contained herein below.

Objection

Claim 7 is objected to because of the following informalities:

Claim 7, the phrase "250mg" should be replaced by "250.0 mg".

Appropriate correction is required.

35 U.S.C. 112, first paragraph rejection

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention of record. The specification, while enabling for treating mitochondria dysfunction occurring in a mammal during aging, does not reasonably provide enablement for prevention or delaying of the said diseases and conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

Theses factors include :

(1) The breadth of the claims;

(2) The nature of the invention;

(3) The state of the prior art;

(4) The level of one of ordinary skill;

(5) The level of predictability in the art;

(6) The amount of direction or guidance provided;

(7) The existence of working examples; and

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

BREATH OF THE CLAIMS

Claims 1 -13 are drawn to pharmaceutical compositions which contain at least one molecule that stimulates energy metabolism of the cell and at least one antioxidant in an amount effective to reduce or prevent oxidative damage resulting from disruption of ATP/ADP; the said composition being used to prevent or restore age-related functional deficits in mammals.

The scope of the claims is seen to include to provide the said composition in a form of a food supplement to a mammal, wherein the said compositions prevent or restore age-related functional deficits in mammals.

STATE OF THE PRIOR ART

The prior art cited by the applicants disclose a composition for improvement of cellular nutrition and mitrochondrial energetics (U.S. Patent 6,080,788). However, there is no disclosure of potential preventive activity seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by the skilled artisans in the field.

THE LEVEL OF ONE OF ORDINARY SKILL IN THE ART

The skilled artisan in this field is that of a MD/ for chemotherapeutic administration and/or a Ph.D. skilled in the development of therapeutics.

THE LEVEL OF PREDICTABILITY OF THE ART

It is noted that the data and examples set forth in the instant disclosure are not sufficient to extrapolate efficacy for the administration of the said composition would have a reasonable expectation of success for preventing the said diseases. There is not seen

sufficient data to substantiate the assertion that the said diseases may be prevented by the use of the composition instantly claimed.

THE AMOUNT OF DIRECTION OR GUIDANCE PROVIDED

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the use of the said compounds to prevent said diseases. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for an advance in treating the said diseases which induces prevention of said diseases.

THE EXISTENCE OF WORKING EXAMPLES

The working examples set forth in the instant specification is drawn to study involving effect of dietary interventions with antioxidants and activators of mitochondria metabolism in a murine model, nutritional formula and pet food. The skilled artisan in this field would not extrapolate the preventive efficacy of the food composition claimed or the use of the same in the preventive methods from just these examples provided. The disclosure does not show the prevention of the said disease. The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Indeed, in view of the information set forth, in the instant disclosure is not seen to be sufficient to enable prevention of the said diseases with the composition set forth in the claims. A skilled artisan would not extrapolate the preventive efficacy from the results disclosed for the examples in mouse and cells, set forth in the instant specification.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **1-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) In claim 1, in the absence of the chemical formula or name of "molecule that stimulates...." and "antioxidant" claimed, the terms "molecule that stimulates...." and "antioxidant" render the claim indefinite wherein applicant fails to articulate by chemical name or structural formula, requisite to identifying the compound of matter claimed.

(B) Claims 2, 12 and 13 are directed to a composition as claimed in claim 1. Claims 2, 12 and 13 do not confer patentable distinction on the previously claimed composition claim 1 therefore claims 2, 12 and 13 are being a substantial duplicate of claim 1. Claims 2, 12 and 13 fail to further limit invention of claim 1.

(C) Claims 3, 6 and 10 are vague and indefinite. Claims 3, 6 and 10 fail to particularly point out the identity of the "natural source".

(D) Claim 9,line 3 is vague and indefinite as it is unclear whether the term "and/or" is intended to be included as 'and' or 'or'.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

35 U.S.C. 103(a) rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims **1-13** are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hamilton et al. (Hamilton) (U.S. Patent 6,562,869) in view of Sears et al. (Sears)(U.S. Patent 6,417,233).

Claims 1-13 are drawn to a food composition comprising at least one molecule that stimulates energy metabolism of the cell in an effective amount and at least one antioxidant in an effective amount.

Additional claim limitations include the molecule selected from L-carnitine, creatine, a monostaurated or polysaturated fatty acid,cardiolipin, nicotinamide,or a carbohydrate or natural source containing such as molecule and the amount of the molecule is between 1mg to 1 g per kg of body weight per day; the antioxidant is selected from lipoic acid, cysteine,cystine, methionine, S-adenosyl-methionine,taurine, glutathione or a natural source and the amount is between 0.025 mg to 250.0 mg per kg of body weight per day; and further antioxidants vitamins C and E, catechins, coffee, spice, grape and soy extracts, ursolic acid, ginseng and prebiotic micro-organism.

Hamilton teaches a composition having anti-aging properties comprising an anti-oxidant, an effective amount of carnitine, a carbohydrate source and vitamins (abstract). Hamilton discloses the use of carnitine and carnitine derivatives as metabolites for

human diet (col. 2, lines 22-24). Hamilton discloses the mitochondrially active antioxidants such as vitamins C and E, lipoic acid, cycteine as human nutritional supplements (col. 2, lines 45-49). The importance of creatine and creatinine in muscle contraction and glucose metabolism is disclosed (col. 4, lines 1-16). Hamilton also discloses the nutritional bar and drink containing carnitine and lipoic acid useful as anti-aging source and to increase energy and stamina, with fewer calories (col. 5, 19-26). Furthermore, Hamilton discloses the preferred amount of carnitine to be between 0.01 g to 1.5 g and the antioxidant of about 1 g or 1 mg to 100 mg (col. 5, lines 43-67). Hamilton differs from the applicant's invention that Hamilton does not provide an example of additional antioxidants such as co-enzymes and fatty acids in the said food composition.

Sears teaches a composition containing co-enzyme Q10 and at least one omega-3- polyunsaturated fatty acid for the prevention and/or treatment of mitrochondriopathies (abstract). Sears discloses that the use of omega-3-polyunsaturated fatty acids enhances the nutritional effects of a co-enzyme (col. 3,lines 22-31).

Therefore, one of ordinary skill in the art would have found the applicants claimed food composition comprising a molecule such as carnitine and an anti-oxidant such as lipoic acid, to have been obvious at the time the invention was made having the above cited references before him. Since Hamilton teaches a food composition having anti-aging properties comprising an effective amount of carnitine, and an anti-oxidant such as lipoic acid, and Sears teaches the use of a composition containing co-enzyme Q10

and at least one omega-3- polyunsaturated fatty acid for the prevention and/or treatment of mitrochondriopathies, one skilled in the art would have a reasonable expectation of success in combining the teachings of Hamilton and Sears to obtain a food composition comprising a molecule that stimulates energy metabolism of the cell and an anti-oxidant to prevent or restore age-related functional deficits in mammals. The motivation is provided by Hamilton reference which discloses that the nutritional bar and drink containing carnitine and lipoic acid are useful as anti-aging source and to increase energy and stamina, with fewer calories (col. 5, 19-26).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
June 4,2004

JAMES O. WILSON
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